PACKAGE LEAFLET

Package leaflet: Information for the patient

Webrix 20 mg film-coated tablets
Webrix 30 mg film-coated tablets
Webrix 40 mg film-coated tablets
Webrix 50 mg film-coated tablets
afatinib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

What is in this leaflet

1. What [PRODUCT NAME] is and what it is used for

[PRODUCT NAME] is a medicine which contains the active substance afatinib. It works by blocking the activity of a group of proteins called the ErbB family (including EGFR [epidermal growth factor receptor or ErbB1], HER2 [ErbB2], ErbB3 and ErbB4). These proteins are involved in the growth and spread of cancer cells and can be affected by changes (mutations) in the genes that produce them. By blocking the activity of these proteins this medicine can inhibit growth and spread of cancer cells.

This medicine is used on its own to treat adult patients with a specific type of cancer of the lung (non-small cell lung cancer):

- that is identified by a change (mutation) in the gene for EGFR. [PRODUCT NAME] can be prescribed to you as your first treatment or if prior chemotherapy treatment has been insufficient.
- of squamous type if prior chemotherapy treatment has been insufficient.

2. What you need to know before you take [PRODUCT NAME]

Do not take [PRODUCT NAME]

- if you are allergic to afatinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- if you are female, have a low body weight of less than 50 kg or have kidney problems. If any of these apply to you, your doctor may monitor you more closely as the side effects may be more pronounced.
- if you have a history of lung inflammation (interstitial lung disease).
- if you have liver problems. Your doctor may do some liver tests. Treatment with this medicine is not recommended if you have a severe liver disease.
- if you have a history of eye problems such as severe dry eyes, inflammation of the transparent layer at the front of the eye (cornea) or ulcers involving the outer part of the eye, or if you use contact lenses.
- if you have a history of heart problems. Your doctor may want to monitor you more closely.

Inform your doctor immediately while taking this medicine:
- if you develop diarrhoea. Treatment at the first signs of diarrhoea is important.
- if you develop skin rash. Early treatment of skin rash is important.
- if you develop new or sudden worsening of shortness of breath, possibly with a cough or fever. These could be symptoms of an inflammation of the lungs (interstitial lung disease) and can be life- threatening.
- if you have severe pain in your stomach or intestines, fever, chills, sickness, vomiting, or abdominal rigidity or bloating, as these could be symptoms of a tear in the wall of your stomach or intestines ('gastrointestinal perforation'). Also, tell your doctor if you had gastrointestinal ulcers or diverticular disease in the past, or are concomitantly treated with anti-inflammatory drugs (NSAIDs) (used to treat pain relief and swelling) or steroids (used for inflammation and allergies), as this may increase this risk.
- if you develop acute or worsening redness and pain in the eye, increased eye watering, blurred vision and/or sensitivity to light. You may need urgent treatment.

See also section 4 "Possible side effects".

Children and adolescents
[PRODUCT NAME] is not recommended for use in children or adolescents. Do not give this medicine to children or adolescents under the age of 18 years.

Other medicines and [PRODUCT NAME]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including herbal medicines and medicines obtained without a prescription.

In particular, if taken before [PRODUCT NAME], the following medicines may increase the blood levels of [PRODUCT NAME] and therefore the risk of side effects. They should therefore be taken as far apart in time as possible from [PRODUCT NAME]. This means preferably 6 hours (for medicines taken twice daily) or 12 hours (for medicines taken once daily) apart from [PRODUCT NAME]:
- Ritonavir, ketoconazole (except in shampoo), itraconazole, erythromycin, nelfinavir, saquinavir - used to treat different kinds of infections.
- Verapamil, quinidine, amiodarone - used to treat heart conditions.
- Cyclosporine A, tacrolimus - medicines that affect your immune system.

The following medicines may reduce the effectiveness of [PRODUCT NAME]:
- Carbamazepine, phenytoin, phenobarbital - used to treat seizures.
- St. John's wort *(Hypericum perforatum)*, a herbal medicine to treat depression.
- Rifampicin, an antibiotic used to treat tuberculosis.

Ask your doctor if you are unsure of when to take these medicines.

[PRODUCT NAME] may increase the blood levels of other medicines including but not limited to:
- Sulfasalazine, used to treat inflammation/infection.
- Rosuvastatin, used for lowering cholesterol.

Tell your doctor before taking these medicines together with [PRODUCT NAME].

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
You should avoid becoming pregnant while taking this medicine. If you could become pregnant, you should use adequate birth control methods during treatment and for at least 1 month after taking the last dose of this medicine. This is because there may be a risk that an unborn baby is harmed.

If you become pregnant while receiving this medicine, you should immediately inform your doctor. Your doctor will decide with you whether treatment should be continued or not.

If you plan to become pregnant after taking the last dose of this medicine, you should ask your doctor for advice as your body may not have fully eliminated this medicine.

Breast-feeding
Do not breast-feed while taking this medicine as a risk to the breast-fed child cannot be excluded.

Driving and using machines
If you experience treatment-related symptoms affecting your eye sight (e.g. redness and/or irritation of the eye, dry eye, tearing, light-sensitivity) or your ability to concentrate and react, it is recommended that you do not drive or use machines until the side effect disappears (see section 4 Possible side effects).

[PRODUCT NAME] contains lactose
This medicine contains a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

[PRODUCT NAME] contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium- free'.

3. How to take [PRODUCT NAME]

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage
The recommended dose is 40 mg each day.

Your doctor may adjust (increase or decrease) your dose depending on how well you tolerate this medicine.

When and how to take [PRODUCT NAME]
- It is important to take this medicine without food
- Take this medicine at least 1 hour before eating, or
- If you have already eaten, wait at least 3 hours before taking this medicine.
- Take this medicine once daily about the same time each day. This makes it easier to remember to take this medicine.
- The blisters containing your tablets are packed in an aluminium pouch with a notch. To open the pouch, pull the different sides of the notch apart. Do not swallow the desiccant sachet that you will find in the pouch.
- Do not break, chew or crush the tablet.
- Swallow the tablet whole with a glass of still water.

[PRODUCT NAME] is to be taken by mouth. If you have difficulties swallowing the tablet, dissolve it in a glass of still water. No other liquids should be used. Drop the tablet into the water without crushing it, and occasionally stir for up to 15 min until the tablet is broken up into very small particles. Drink the liquid straight away. Then fill the glass again with water and drink it to make sure all medicine is taken.

If you are not able to swallow and have a gastric tube your doctor might suggest that the medicine is given to you via the tube (CH8 or greater). It is not necessary to flush the nasogastric tube through with water after administration of the dispersion.

If you take more [PRODUCT NAME] than you should
Contact your doctor or pharmacist immediately. You may experience increased side effects and your doctor may interrupt your treatment and provide supportive care.

If you forget to take [PRODUCT NAME]

- If your next scheduled dose is more than 8 hours away, take the missed dose as soon as you remember.
- If your next scheduled dose is due within 8 hours, skip the missed dose and take your next dose at the usual time. Then carry on taking your tablets at regular times as usual.

Do not take a double dose (two tablets instead of one at the same time) to make up for a missed dose.

If you stop taking [PRODUCT NAME]
Do not stop taking this medicine without first consulting your doctor. It is important to take this medicine every day, as long as your doctor prescribes it for you. If you do not take this medicine as prescribed by your doctor your cancer may grow again.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, [PRODUCT NAME] can cause side effects, although not everybody gets them.

Contact your doctor as soon as possible if you suffer from any of the serious side effects listed below. In some cases your doctor may need to interrupt treatment and reduce your dose or stop treatment:

- **Diarrhoea** (very common, may affect more than 1 in 10 people).
  Diarrhoea lasting more than 2 days or more severe diarrhoea may lead to fluid loss (common, may affect up to 1 in 10 people), low blood potassium (common) and worsening kidney function (common). Diarrhoea can be treated. At the first signs of diarrhoea drink plenty of fluids. Contact your doctor immediately and start appropriate antidiarrhoeal treatment as soon as possible. You should have antidiarrhoeal medicine available prior to taking [PRODUCT NAME].

- **Skin rash** (very common).
  It is important to treat the rash early. Tell your doctor if a rash starts. If treatment for rash is not working and the rash is getting more severe (for example, you have peeling or blistering of the skin) you should notify your doctor immediately, since your doctor may decide to stop your treatment with [PRODUCT NAME]. Rash may occur or worsen in areas exposed to sun. Sun protection with protective clothing and sunscreen is recommended.

- **Inflammation of the lungs** (uncommon, may affect up to 1 in 100 people) called “interstitial lung disease”. Tell your doctor immediately if you develop new or sudden worsening of shortness of breath, possibly with a cough or fever.

- **Eye irritation or inflammation**
  Eye irritation or inflammation may occur (conjunctivitis/dry eye occurs commonly and keratitis uncommonly). Tell your doctor if you have sudden or worsening of eye symptoms such as pain or redness or dry eye.

If you experience any of the symptoms above, contact your doctor as soon as possible. The following other side effects have also been reported:

Very common side effects (may affect more than 1 in 10 people):
- Mouth sores and inflammation
- Nail infection
- Decreased appetite
- Bleeding from the nose
- Nausea
- Vomiting
- Itching
- Dry skin

Common side effects (may affect up to 1 in 10 people)**:**
- Pain, redness, swelling or peeling of the skin of your hands and feet
- Increased levels of the liver enzymes (aspartate aminotransferase and alanine aminotransferase) in blood tests.
- Inflammation of the lining of the bladder with burning sensations during urination and frequent, urgent need to urinate (cystitis)

- Abnormal taste sensations (dysgeusia)
- Stomach pain, indigestion, heartburn
- Lip inflammation
- Decreased weight
- Runny nose
- Muscle spasms
- Fever
- Nail problems

Uncommon side effects (may affect up to 1 in 100 people)**:**
- Inflammation of the pancreas (pancreatitis)
- Occurrence of a tear in the wall of your stomach or intestines (gastrointestinal perforation)

Rare side effects (may affect up to 1 in 1,000 people)**:**
- Severe blistering or peeling of skin (suggestive of Stevens-Johnson syndrome and toxic epidermal necrolysis)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [PRODUCT NAME]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, the pouch and the blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information What [PRODUCT NAME] contains

- The active substance is afatinib.

[PRODUCT NAME] 20 mg film-coated tablets:
- Each film-coated tablet contains afatinib dimaleate equivalent to 20 mg afatinib.
- The other ingredients are lactose, crospovidone, cellulose microcrystalline, mannitol, colloidal anhydrous silica, sodium stearyl fumarate, hypromellose (E464), titanium dioxide (E171), talc (E553b), macrogol (E1521), polysorbate 80 (E433).

[PRODUCT NAME] 30 mg film-coated tablets:
- Each film-coated tablet contains afatinib dimaleate equivalent to 30 mg afatinib.
- The other ingredients are lactose, crospovidone, cellulose microcrystalline, mannitol, colloidal anhydrous silica, sodium stearyl fumarate, hypromellose (E464), titanium dioxide (E171), talc (E553b), macrogol (E1521), polysorbate 80 (E433), Indigo Carmine Aluminum Lake (E132).

[PRODUCT NAME] 40 mg film-coated tablets:
- Each film-coated tablet contains afatinib dimaleate equivalent to 40 mg afatinib.
- The other ingredients are lactose, crospovidone, cellulose microcrystalline, mannitol, colloidal anhydrous silica, sodium stearyl fumarate, hypromellose (E464), titanium dioxide (E171), talc (E553b), macrogol (E1521), polysorbate 80 (E433), Indigo Carmine Aluminum Lake (E132).

[PRODUCT NAME] 50 mg film-coated tablets:

- Each film-coated tablet contains afatinib dimaleate equivalent to 50 mg afatinib.
- The other ingredients are lactose, crospovidone, cellulose microcrystalline, mannitol, colloidal anhydrous silica, sodium stearyl fumarate, hypromellose (E464), titanium dioxide (E171), talc (E553b), macrogol (E1521), polysorbate 80 (E433), Indigo Carmine Aluminum Lake (E132).

What [PRODUCT NAME] looks like and contents of the pack

[PRODUCT NAME] 20 mg film-coated tablets are white to yellowish, round, biconvex, film-coated tablets, debossed with “20” on one side and plain on the other with a nominal diameter of 8.1 mm.
[PRODUCT NAME] 30 mg film-coated tablets are dark blue, round, biconvex, film-coated tablets, debossed with “30” on one side and plain on the other with a nominal diameter of 9.1 mm.
[PRODUCT NAME] 40 mg film-coated tablets are light blue, round, biconvex, film-coated tablets, debossed with “40” on one side and plain on the other with a nominal diameter of 10.1 mm.
PRODUCT NAME] 50 mg film-coated tablets are dark blue, oval, biconvex, film-coated tablets, debossed with “50” on one side and plain on the other with a nominal length of 15.2 mm and a nominal width of 7.1 mm.

[PRODUCT NAME] film-coated tablets are available in packs containing 1, 2 or 4 PVC/PVDC/aluminium blisters. Each blister contains 7 film-coated tablets and is packed in an aluminium pouch together with a desiccant sachet that should not be swallowed.
[PRODUCT NAME] film-coated tablets are available in packs containing 1, 2 or 4 PVC/PVDC/aluminium perforated unit dose blisters. Each blister contains 7 x 1 film-coated tablets and is packed in an aluminium pouch together with a desiccant sachet that should not be swallowed.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

<to be completed nationally>

Manufacturer

<to be completed nationally>

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